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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,181	04/26/99	BRACCO L	ST96030-US

005487 HM12/0718
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EXAMINER	
CONNELL, Y	
ART UNIT	**PAPER NUMBER**
1633	7

DATE MAILED: 07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/297,181	Bracco et al
Examiner	**Group Art Unit**
Yvette Connell Albert	1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *28-54* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *28-54* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 28, 30-32, 40-44, drawn to methods of restoring p53 transactivation in a cell, via single chain antibody binding to mutated p53, classified in class 514, subclass 2.

II. Claims 28-29, and 33-43, drawn to methods of restoring p53 transactivation in a cell, via a nucleic acid which comprises a sequence encoding the single chain antibody, classified in class 514, subclass 44.

III. Claim 45 drawn to a method for modifying the conformation of a mutated p53, classified in class 435 subclass 7.1.

IV. Claims 46, 47, and 54, drawn to methods of treating a hyper proliferative disorder, via a single chain antibody binding mutated p53 and nucleic acid encoding single chain antibody binding mutated p53, and a pharmaceutical composition comprising the nucleic acid, classified in class 514, subclasses 2 and 44.

V. Claims 48 and 53, drawn to an antibody and composition comprising antibody, classified in class 424, subclass 138.1.

VI. Claims 49-52, drawn to a nucleic acid encoding an antibody, and compositions comprising nucleic acid, classified in class 536, subclass 23.1.

Claims 28 and 40-44 are generic to groups I and II. Upon election of either group I or II, the claims will be examined only in so far as they read on the elected invention. Additionally, if groups I or II is elected, the claims must be amended to read on the elected invention, since after election they will contain non-elected subject matter.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are distinct from invention IV because the methods of restoring p53 transactivation via antibodies and nucleic acids encoding antibodies, and the method of modifying p53 conformation via antibodies, all involve in vitro cellular effects and manipulations, and is distinct from the methods of treating a hyper proliferative disorder in a patient involving in vivo delivery systems, which require different technical considerations and reagents, which elicits an immune response, not associated with in vitro cellular manipulations. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions V and VI are distinct because the antibodies of invention V are distinct in chemical structure, function, as well as therapeutic function, from the nucleic acids of invention VI. Furthermore, the antibodies of invention V can be used in screening assays, while the nucleic acids of invention VI can be used as hybridization probes for screening cDNA and genomic libraries. The differences between the inventions are further underscored by their divergent classification and independent search status.

Inventions I-III, V-VI, and IV are related in that they all utilize the single chain antibody and/ or nucleic acid of inventions V-VI, to restore or modify p53 in inventions I-III, and to treat

hyper proliferative disorders in invention IV. However, the inventions, I-III and V-VI, are distinct from invention IV, because invention IV is directed solely to *in vivo* manipulations, the technical considerations, reagents and manipulations of which are not involved in *in vitro* cellular manipulations of inventions I-III and V-VI. The differences between the inventions are further underscored by their divergent classification and independent search status.

If applicants elect group IV, a further election is required for claims 46, 47, and 54, since they are generic to nucleic acids and antibodies. Group A: 46, 47, and 54 - Antibody. Group B: 46, 47, and 54 - Nucleic acid. Invention A is distinct from invention B because: the antibodies of invention A are distinct in chemical structure, function, as well as therapeutic function, from the nucleic acids of invention B. Furthermore, the antibodies of invention A can be used in screening assays, while the nucleic acids of invention B can be used as hybridization probes for screening cDNA and genomic libraries. The differences between the inventions are further underscored by their divergent classification and independent search status.

Upon election of group IV and the further election between nucleic acid or antibody, the claims of group IV will be examined only in so far as they read upon the further election, since the claims of group IV are generic. Further, upon such election, the claims of group IV must be amended accordingly since they will contain non-elected subject matter upon the further election.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvette Connell, whose telephone number is 703-308-7942. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447.

Any inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Yvette Connell

June 30, 2000

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600